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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,667	10/29/2001	Soumya P. Sahoo	20768	7049

7590 11/25/2002

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EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Resp not in Conformation c̄ Office Action requiring applicant to adopt the species and the same and submitting an affidavit thereof.

Regard to Restriction:

- Search c̄ G = O, S, N => X a Y alkyl[1-6]
- Call applicant to limit het in claims 19 & 22.
- check 09/961,841 for the claims

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	10/021,667	SAHOO ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detail Action

Election/Restrictions

Claims 1-55 are generic to a plurality of disclosed patentably distinct species comprising compounds of formulae I and Ia. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for search purpose, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the invention.

1. A telephone call was made to James McGinnis on 11/5/02, to request an oral election of a species compound for search purpose. Example 6, on pages 47 and 87, was elected. Affirmation of this election must be made by applicant in replying to this Office action.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases such as diabetes or Alzheimer's, does not reasonably provide enablement for their "prevention". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. There is no known compound for the prevention of diabetes, and the specification does not provide sufficient enabling disclosure for the claimed utility.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

1) Breadth of claims.

2) Nature of invention.

3) State of prior art.

4) Level of ordinary skill in the art.

5) Level predictability in the art.

6) Amount of direction and guidance provided by the inventor.

7) Existence of working examples.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involve the use of compounds of formulae I and Ia. The nature of the invention is in the field of medicinal chemistry wherein applicant is claiming the methods of use of the compounds for the prevention of diabetes II or Alzheimer's disease.

The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming the prevention of diabetes II or Alzheimer's disease. The level of ordinary skill in the art is high but only in the art of treating diabetes or Alzheimer's disease. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assays involving: 1) PPAR binding assay, 2) Gal-4 hPPAR transactivation assay, and 3) in vivo studies. None of the studies has results, analyses and/or interpretations of the results, and conclusions thereof. There is no evidence in the specification that established correlation between the experiments and prevention of diabetes or Alzheimer's disease. See Ex parte Mass, 9 USPQ2d 1746, 1987. The entire disclosure in the specification is directed toward treating and not preventing diabetes. Therefore, the quantity of experimentation required to use the compounds as claimed in the instant invention, based on applicants limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo experiments as well as additional in-vitro assays. By deleting "prevention" from the claims, the rejection would be overcome.

Claims 45-46, 48-49, 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims rely on several patents cited in the specification, page 5, lines 11-15, for support. The patents are not incorporated by reference. Applicant must incorporate the reference in accordance with MPEP, which states as follows: A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky,* 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to specific portions (description of the subject matters, at what page and on which line) of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

The terms "Syndrome X" "ZD-4522, MCC-555, and "KRP-297" are not defined in the specification on first occurrence according to standard scientific practice. Therefore, it is not possible to ascertain what applicant is claiming by the terms in claims 45-46, 48-49, 53 and 55.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 17-18, 29-30, 33-34, 45-46, 48-49, 53, 55, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-18 fail to recite what is being claim as required under US patent practice. Instead, the claims recite what is not claimed on lines 1-2. These and other similar claims must be written to recite what applicant is claiming.

Claims 29-30 are indefinite because claim 29 is an independent claim but rely on claim 1 for the definition of the substituents of formula Ia. Claim 29 must stand alone to define the invention. Appropriate correction is required.

Claims 33-34 are duplicates because they are drawn to the same set of species. Claim 33 recites the formulae of the compounds while claim 34, recites their names. Also, claim 33 listed the structures in a table contrary to acceptable standard under US patent practice. By deleting claim 33 the rejection would be overcome. "Example 1: – 29:" in claim 34 should be deleted.

The terms "Syndrome X" "ZD-4522, MCC-555, and "KRP-297" are not defined in claims 45-46, and therefore claims 45-46, 48-49, 53, 55, are indefinite.

Claims 45-46, 48-49, 55 are rejected for being indefinite. The claims recite several patents as sources of what applicant is claiming. A claim must stand alone to define the invention, and incorporation into the claim by express reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-55 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-46 of copending Application No. 09/961,841. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

However, after amending the claims as suggested below applicant may overcome this rejection by filing a terminal disclaimer.

Allowable Subject Matter

To place the application in condition for allowance, the claims must be amended with the following limitations:

1) Formulae I and Ia wherein, R1 is $-CR^{11}R^{12}-$, and forms a cyclopropane ring with the adjacent ring carbon.

2) The claims must have no further heterocyclic substituents.

3) No further substituent at position R1.

4) The definitions of other substituents must be within the scope of formulae I and Ia with no heterocyclics.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and the best days to get him are Mondays, Tuesdays, Thursdays and Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

November 21, 2002